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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/460,878	02/02/90	EKINS	R

EXAMINER	
WOODWARD, M	

ART UNIT	PAPER NUMBER
187	3

DATE MAILED: 05/31/91

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-11 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-11 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ 157; In re Hawkins, 486 F.2d 579, 179 USPQ 163; In re Hawkins, 486 F.2d 577, 179 USPQ 167.

The attempt to incorporate subject matter into this application by reference to WO88/01058 is improper because the steps and the methodology disclosed in the published application appear to be essential to the practice of the instant invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicant begins the disclosure by stating that under conditions where the total amount of ligand bound is "insignificant" compared to the total ligand concentration that measurements of bound ligand are effectively independent of volume. This is true depending on what constitutes insignificant. However, the argument stems from first principles and the law of mass action. It needs to be clearly established

when the departure from insignificance occurs.

Applicant then argues that employing low levels of antibody such that the concentration of antigen is effectively unchanged by antigen bound to antibody is "contrary to generally recommended practice in the field of immunoassay." This argument is misleading. It is true that a segment of the workers in the field of immunoassay have developed a particular standardized fashion for measurement; applicant has played a significant role in this area, even as late as 1985 (Dudley et al.). The teaching of the art is that the apparently optimal conditions for a sensitive, reliable immunoassay are those in which approximately 50 percent of the tracer is bound. This is not a teaching that other methods will not work.

Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 what does loading mean? The way the loading is described a single spot could have more than one binding agent in it. Is this what applicant intends as opposed to each spot containing a single binding agent? The second step of the method reads on samples in individual wells as well as many samples in one well. What is meant by same operation? What constitutes insignificant proportion?

In claim 5 the range set includes zero volume which clearly could not work.

The following is a quotation of 35 U.S.C. § 103 which forms

the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-11 rejected under 35 U.S.C. § 103 as being unpatentable over applicant's own admissions of the prior art. On page 1 of the specification applicant states that in WO84/01031 he proposed making quantitative measurements of analytes using trace amounts of specific antibodies and on page 3 it is disclosed that UK Patent Application 2,099,578A concerns a device for analysing a plurality of specimens. A similar device is disclosed in Chang (US Patent 4,591,570). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to simultaneously quantify several analytes using trace levels of antibody in a device such as that described by Chang because it would be expected to work.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Woodward whose telephone number is (703) 308-3908.

Any inquiry of a general nature or relating to the status of

this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
ART UNIT 187